

**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEXES V and VI
concerning feed materials, additives/processing aids and certain substances used in animal
nutrition of Commission Regulation (EC) No 889/2008**

Articles 16.3 b of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."

General information on the request

Nature of the request	<input type="checkbox"/> Inclusion <input type="checkbox"/> Deletion <input type="checkbox"/> Change of disposition
Request introduced by	[Member State] Contact e-mail:
Date	

Please indicate if the material provided is confidential

Requested inclusion/deletion/amendment

Name of additive / substance	Primary use/conditions

1. Identification ¹

Common name
Name(s) of active substance
Other names
Trade names
CAS ² No.

¹ To be filled in only when applicable

² Chemical Abstracts Systematic Names

IUPAC ³ Name
E.C Additive Identification No
Other code(s)

2. Characterisation ⁴

Chemical formula/composition of active substance
Concentration of active substance
If preparation, other components
Physical properties
Origin, inputs and production method of the active substance
Method(s) of analysis

3. Specification of use

Material/additive category
Material/additive functional group
Species groups

³ International Union of Pure & Applied Chemistry

⁴ To be filled in only when applicable

Minimum or maximum rate according to species group (if appropriate)
Method of application

4. Status

Authorization in general agriculture or food processing

Historic use
Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable)

5. Reasons for the inclusion, withdrawal or amendments,

Specify in which Annex the inclusion, withdrawal or amendments is requested

V VI

Explain the need for the proposed feed material or additive change
What alternative solutions are currently authorised or possible?
Is there any traditional use or precedents in organic production?

6. Consistency with objectives and principles of organic production

Please use the check list in Annex A to this dossier to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

7. Other aspects

Environment
Animal health and welfare
Human health
Food quality and authenticity
Various aspects, further remarks

8. Annexes

9. References

Annex A

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulation

Criterion	Specific articles in Reg. 834/2007	Yes/No/ Not applicable	Brief qualification
Exclude the use of GMOs and products produced from or by GMOs	Art. 9 Art. 4(a)(iii)		
Is it a synthetic amino acid ?	Art. 14 (1) (d) (v)		
Is it a growth promoter?	Art. 14 (1) (d) (v)		
Aim at producing a wide variety of foods and other agricultural products.....goods produced by the uses of processes that do not harm the environment, human health, plant health or animal health and welfare.	Art 3 (c)		
Aim at producing products of high quality	Art. 3(b)		
Is it natural (not chemically synthesised)?	Art. 4(b) and (c) Art. 16(2)(e) (ii)		
Their use is necessary for sustained production and essential for its intended use, and general and specific criteria has been evaluated	Art. 16(2)(a)(e)		
Does it have nutritional value?	Art 14(1)(d)(ii)		
Is it a natural milk replacer?	Art. 14 (1) (d) (vi)		
Is it of agricultural origin?	Art. 5 (k) Art. 14 (1) (d) (iv)		
Is it produced organically?	Art. 14 (1) (d) (i) and (iv)		
Is it land-based/using natural internal resources?	Art. 4 (a) and (b) Art. 5 (g)		
Is it aquaculture which complies with the principle of sustainable fisheries/using natural internal resources?	Art. 5 (o) Art. 4 (a) (b) and Art. 5 (g)		
The recycling of wastes and by-products of plant and animal origin as input in plant and livestock production	Art. 5 (c)		
Is it produced internally (primarily from the holding where animals are kept or from other holding in the same region?	Art. 14(1) (d) (i)		

Does it affect the permanent access to pasture ?	Art. 14 (1) (d) (iii)		
Does it restrict the use of additives and processing aids?	Art. 7 (b)		
Is it species appropriate?	Art. 16.2(e)(i)		
Does it have negative environmental impacts?	Art. 3 (a) (i) and Art. 4 (c) (iii)		
Does it have negative animal health/welfare impacts?	Art. 5 (h) and art. 14 (e) (i)		
Does it have negative human health impacts?	Art. 3 (b) and (c)		
Does it involve 'misleading' substances/processes?	Art. 7 (c) and Art. 18 (4)		
Products and substances to be withdrawn or their use amended/limited	Art .21 (2)		
Others: please specify			